# EXHIBIT 33

## **M**SKESSON

# **Controlled Substance Monitoring**Discount Drug Mart

September 29<sup>th</sup>, 2017

#### **Nate Hartle**

Sr. Director - Regulatory Affairs



#### **MCKESSON**

# Agenda



## **Scope of Problem**

Industry Updates
Regulatory Responsibilities
McKesson's CSMP
Discount Drug Mart Program Overview
Q & A | Open Discussion

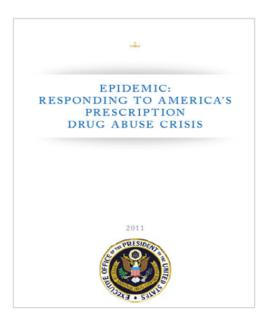
## Scope of the Problem | Epidemic

#### **M**CKESSON

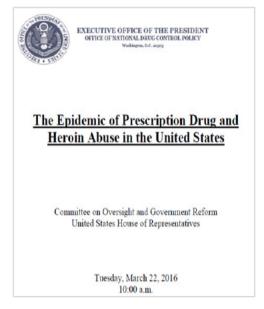


# DEADLIEST DRUG EPIDEMIC ON RECORD IN OUR NATION'S HISTORY

"The drug problems of past decades pale when compared to the current opioid epidemic which has killed 165,000 Americans from 2000 to 2014."



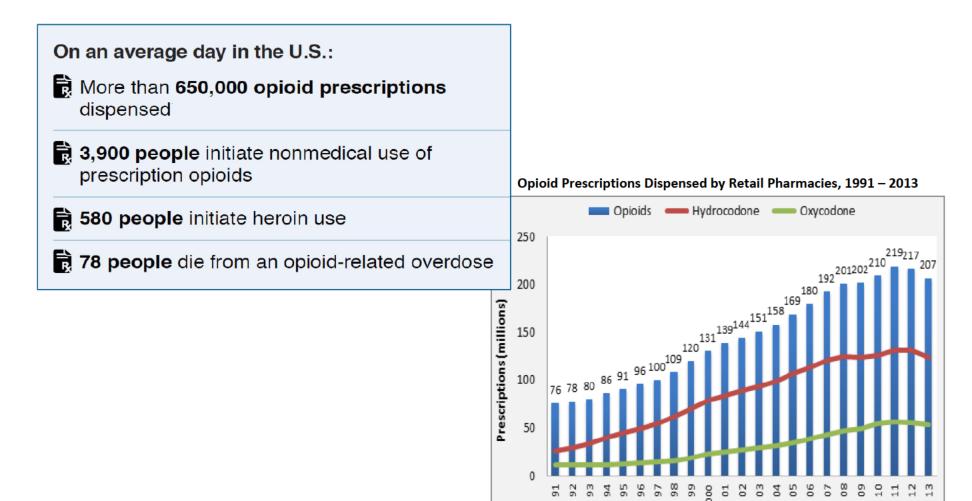




Source: National Safety Council. Prescription Nation 2016: Addressing America's Drug Epidemic. Retrieved November 7, 2016, from National Safety Council: http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf

## Scope of the Problem | Opioid Prescribing & Abuse

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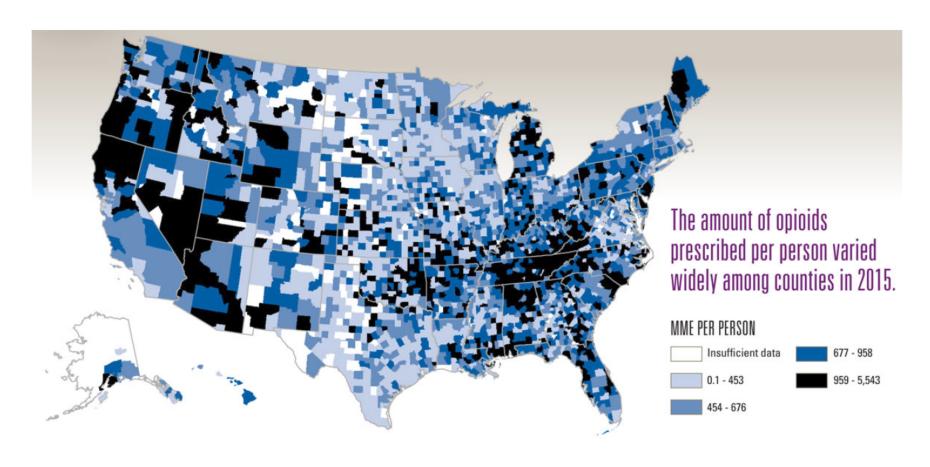


Source 1: Department of Health & Human Services. The Opioid Epidemic: By the Numbers. Retrieved November 7, 2016, from Department of Health & Human Services: http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf

Source 2: NIH: National Institute on Drug Abuse. Prescription Opioid & Heroin Abuse. Retrieved November 14, 2016, from NIH: National Institute on Drug Abuse: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/prescription-opioid-heroin-abuse

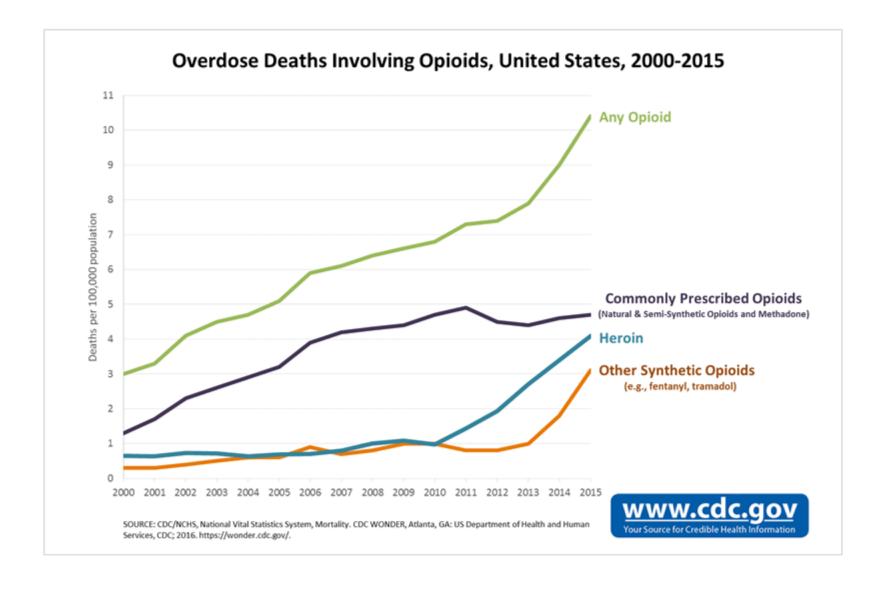
# Scope of the Problem | Opioid Prescribing & Abuse

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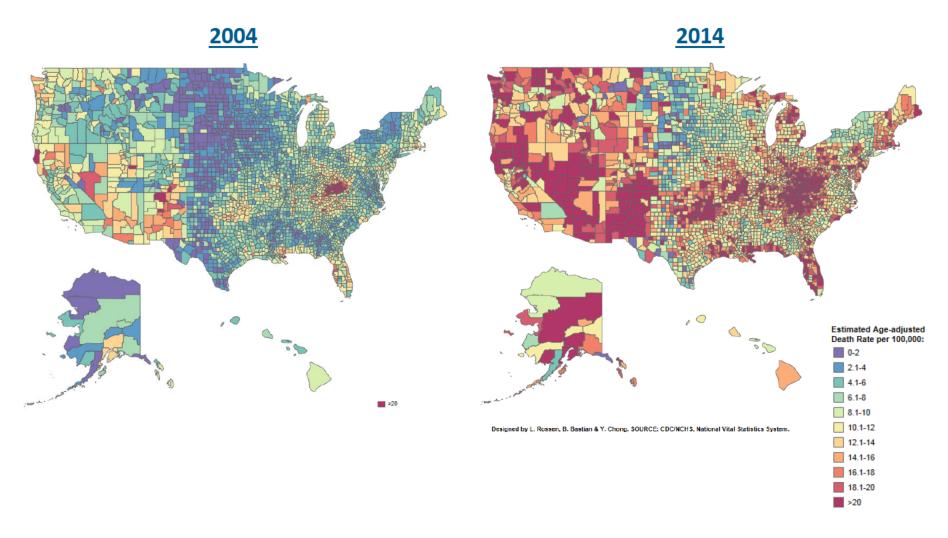
Source: Centers for Disease Control and Prevention, Vital Signs July 2017. Opioid Prescribing – Where you live matters. Retrieved August 22, 2017 from Centers for Disease Control and Prevention: https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf

# **Scope of the Problem | Overdose Death Statistics**



# **Scope of the Problem | Overdose Death Statistics**

### **M**CKESSON

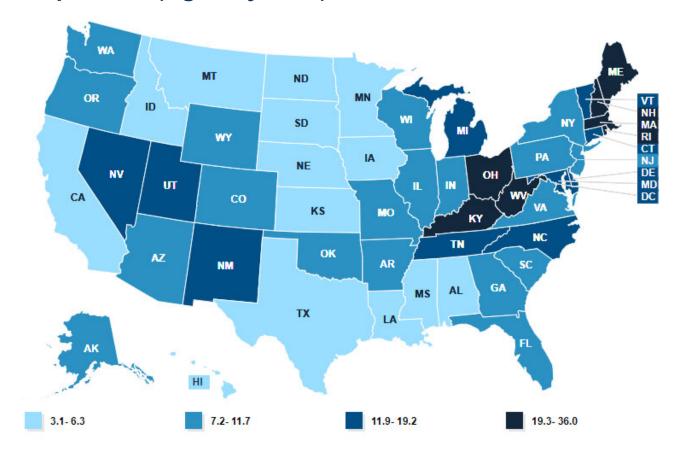


Source: Centers for Disease Control and Prevention, NCHS Data Visualization Gallery. *Drug Poisoning Mortality: United States, 1999–2014*. Retrieved November 14, 2016, from Centers for Disease Control and Prevention: https://blogs.cdc.gov/nchs-data-visualization/drug-poisoning-mortality/

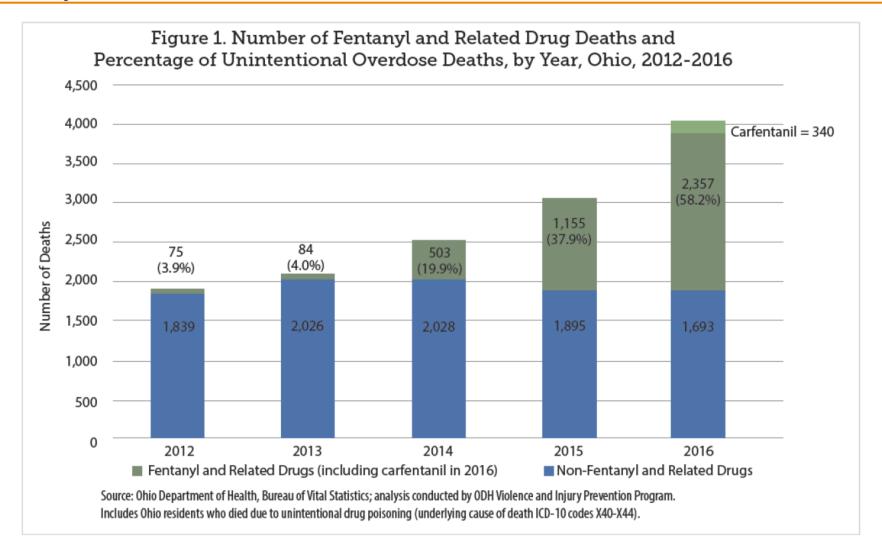
## **Scope of the Problem | Overdose Death Statistics (2015)**

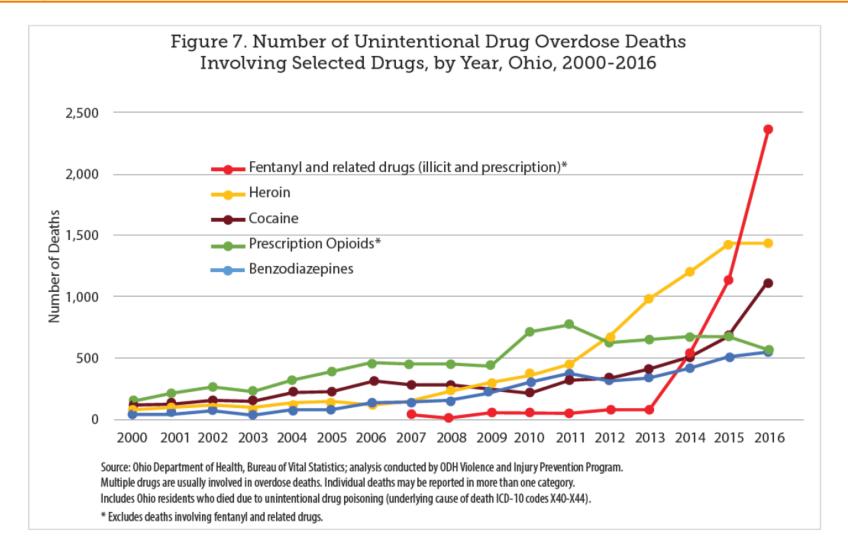
### **MCKESSON**

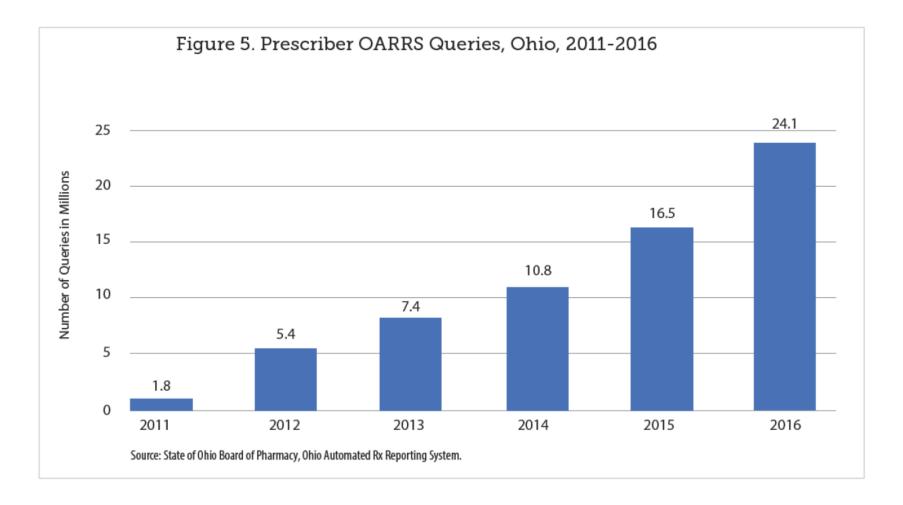
# Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted)

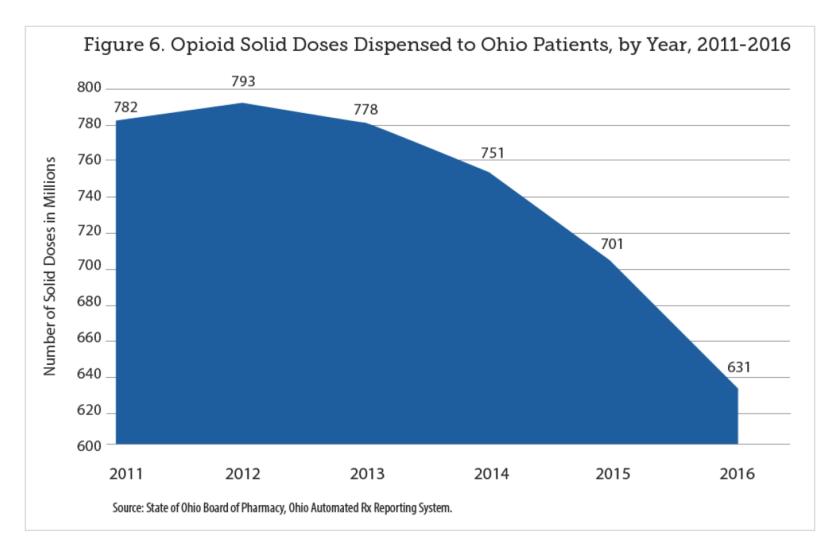


Source: Kaiser Family Foundation analysis of Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Multiple Cause of Death 1999-2015 on CDC WONDER Online Database, released 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://www.kff.org/other/state-indicator/opioid-overdose-death-rates on August 23, 2017.









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# Agenda



Scope of Problem

## **Industry Updates**

Regulatory Responsibilities

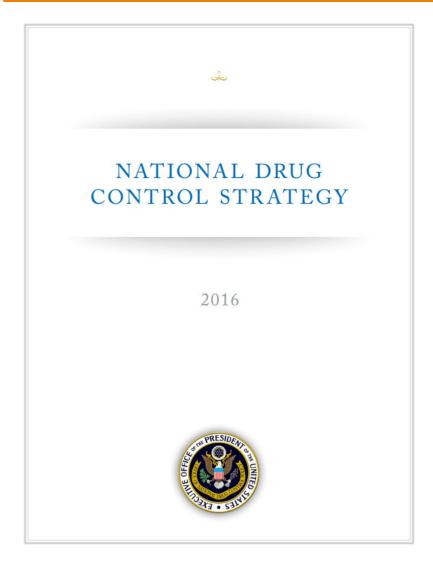
McKesson's CSMP

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## **Industry Updates | National Drug Control Strategy**

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**Policy Focus:** Preventing and Addressing **Prescription Drug** Misuse and **Heroin** Use

## **Four Pillars:**

- 1. Education
- 2. Monitoring
- 3. Disposal
- 4. Enforcement

Source: Office of National Drug Control Policy. 2015 National Drug Control Strategy. Retrieved February 10, 2016, from Office of National Drug Control Policy: https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/2015\_national\_drug\_control\_strategy\_0.pdf

## **Industry Updates | DEA 360 Strategy**

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#### DEA 360 Strategy

Working Together to Break the Cycle of Drug Trafficking, Drug Violence, and Drug Abuse

#### What is DFA 3603

A comprehensive approach tackling the cycle of violence and addiction generated by the link between drug cartels, violent gangs, and the rising problem of prescription opioid and heroin abuse in U.S. cities. DEA 360 involves:



- Coordinated Law Enforcement operations targeting all levels of drug trafficking organizations and violent gangs supplying drugs to our neighborhoods
- Engaging drug manufacturers, wholesalers, practitioners, and pharmacists through
   Diversion Control to increase awareness of the opioid epidemic and encourage responsible
   prescribing practices, and use of opioid painkillers throughout the medical community
- Community Outreach and partnership with local organizations following enforcement
  operations, equipping and empowering communities to fight the opioid epidemic

#### National Partners with Local Reach:

- . U.S. Attorney's Office Pittsburgh
- . Boys & Girls Clubs of America
- · Community Anti-Drug Coalitions of America
- DEA Educational Foundation
- DOJ Violence Reduction Network
- · The Elks Club

#### HHS - Substance Abuse and Mental Health Services Administration

- White House Office of National Drug Control Policy
- · Partnership for Drug-Free Kids

#### Goals:

- Stopping the deadly cycle of heroin and opioid pill abuse by eliminating drug trafficking organizations and gangs fueling violence on the streets and cycles of addiction in our communities
- Partnering with the medical community and others to raise awareness of the dangers of prescription opioid misuse and the link to heroin
- Strengthening community organizations best positioned to provide long-term help and support for building drug-free communities



For more information: Contact DEA Public Affairs at (202) 307-7977

# Strategy for **prescription opioid** and **heroin** abuse:

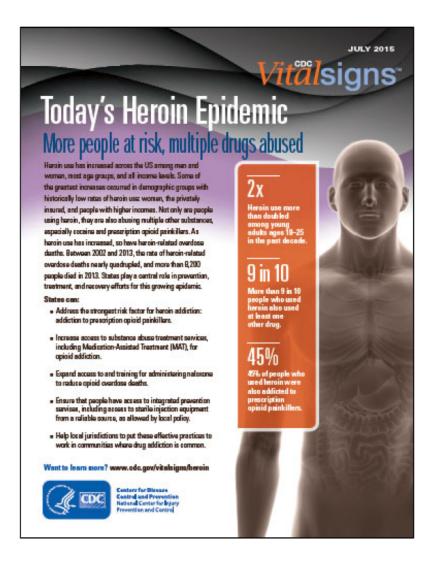
- ✓ Enforcement: A commitment to stopping violence associated with drug trafficking
- ✓ **Diversion**: Enlisting DEA's registrant population in the fight against opioid abuse
- ✓ Community: Leaving something lasting and positive in the communities DEA serves

Pilot in West Memphis, AR, St. Louis, MO, Pittsburgh, PA, Milwaukee, WI

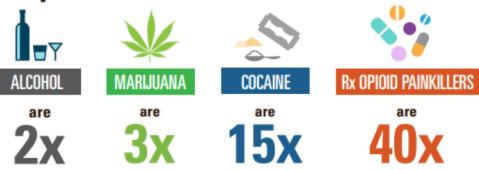
Source: Statement of Louis J. Millione, Deputy Assistant Administrator, Office of Diversion Control, DEA before the Committee on the Judiciary, United States Senate, for a Hearing entitled "Attacking America's Epidemic Of Heroin And Prescription Drug Abuse" presented January 27, 2016. http://www.dea.gov/divisions/hq/2015/hq111015-DEA%20360%20Strategy%20Fact%20Sheet.pdf, Accessed February 10, 2016.

## **Industry Updates | Today's Heroin Epidemic**

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## People who are addicted to...

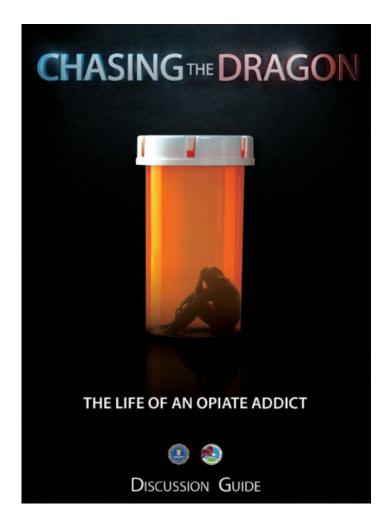


...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

Source: Centers for Disease Control and Prevention, Vital Signs July 2015. *Today's Heroin Epidemic*. Retrieved February 10, 2016, from Centers for Disease Control and Prevention: http://www.cdc.gov/vitalsigns/pdf/2015-07-vitalsigns.pdf

## **Industry Updates | Chasing the Dragon**



**Chasing the Dragon** is a documentary film from DEA and FBI;

- ✓ Aimed at educating high school students & young adults of the dangers of addiction
- ✓ Message is deterrence since opioid addiction can take hold after first use

Source: FBI National Press Office. FBI, DEA Release Documentary Film Addressing Heroin/Prescription Drug Abuse. Retrieved February 10, 2016, from FBI: https://www.fbi.gov/news/pressrel/press-releases/fbi-dea-release-documentary-film-addressing-heroin-prescription-drug-abuse

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# Agenda



Scope of Problem
Industry Updates

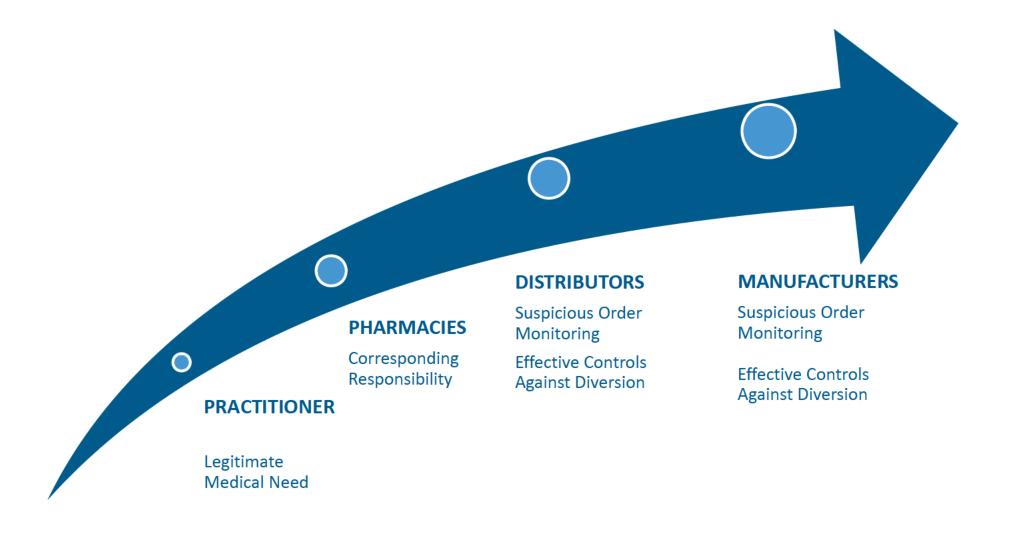
## **Regulatory Responsibilities**

McKesson's CSMP
Discount Drug Mart Program Overview
Q & A | Open Discussion

## **Regulations | The Supply Chain**

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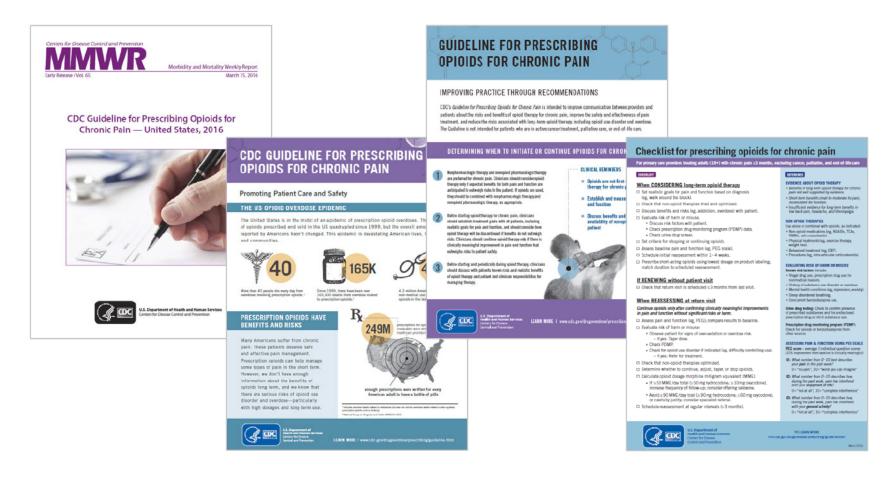
Prescription drug abuse is a national problem, requiring an industry-wide solution.



## **CSA Checks & Balances | Practitioners**

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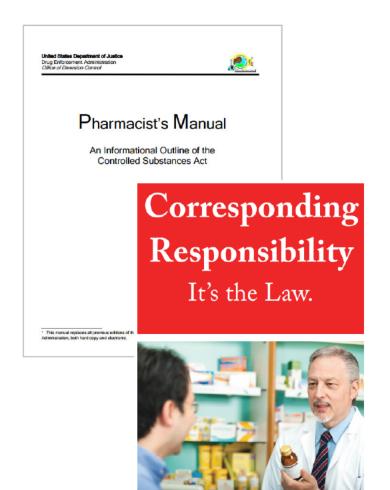
"A prescription for a controlled substance to be effective must be issued for a **legitimate medical purpose** by an individual practitioner acting in the usual course of professional practice." (21 CFR §1306.04(a))



## **CSA Checks & Balances | Pharmacists**

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"The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." (21 CFR § 1306.04(a))





## **CSA Checks & Balances | Distributors & Manufacturers**

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"Maintenance of **effective controls against diversion** of particular controlled substances into other than legitimate medical, scientific, and industrial channels..." (21 U.S.C. §823/21 CFR §1301.71(a))



"The registrant shall **design** and **operate** a system to disclose to the registrant **suspicious orders** of controlled substances. . . . Suspicious orders include orders of unusual **size**, orders deviating substantially from a normal **pattern**, and orders of unusual **frequency**." (21 CFR §1301.74(b))

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# Agenda



Scope of Problem
Industry Updates
Regulatory Responsibilities

## McKesson's CSMP

Discount Drug Mart Program Overview
Q & A | Open Discussion

## **McKesson CSMP | Mission & Operating Principles**

### **M**CKESSON

U.S. Pharma Controlled Substance Monitoring Program

#### Mission Statement

Our mission is to manage U.S. Pharma's Controlled Substance Monitoring Program as a nationwide regulatory compliance program that is informed by diversion trends and our customers. Through our program, we strive to strengthen the understanding of the prescription drug abuse epidemic across the industry with dialogue and collaboration.



U.S. Pharma Controlled Substance Monitoring Program

## **Operating Principles**

As we continue to design our program, we will adhere to the following operating principles:

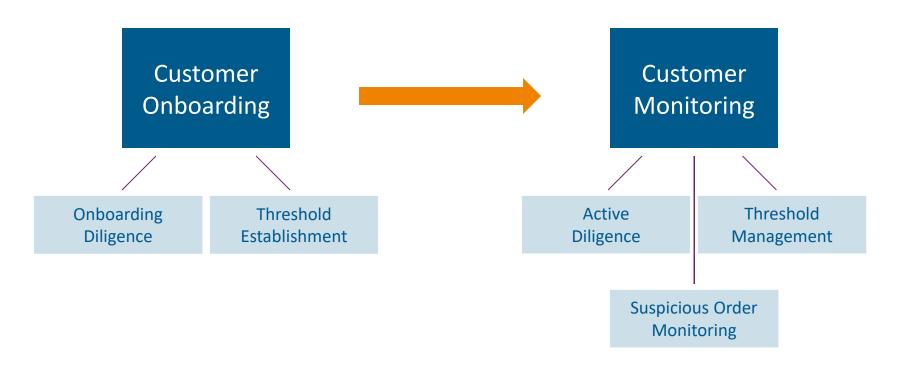
- Risk-based Comprehensively covers all controlled substances and all customers, while driving the greatest focus on those presenting a higher risk of diversion.
- Uniform Generates consistent execution against nationwide standards and requirements.
- **Sustainable** Achievable over the long term.
- Contemporary Refreshed on an ongoing basis to address current diversion trends, while reflecting the legitimate business models of our customers as they evolve.
- Defined Meets regulations as they are applicable to wholesalers. Other registered entities in the supply chain have their own independent responsibility to achieve compliance.

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## McKesson CSMP | Design/Framework

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Statistics, Analytics, and Diversion Trends

## McKesson CSMP | RNA Team

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Nate Hartle Sr. Director Minneapolis, MN



Michael Oriente Director Philadelphia, PA



Adam Palmer Sr. Manager Indianapolis, IN



Micheal Bishop Manager Las Colinas, TX



Adam Shepherd Regulatory Assistant Las Colinas, TX

## Sr. Director Leadership Background:

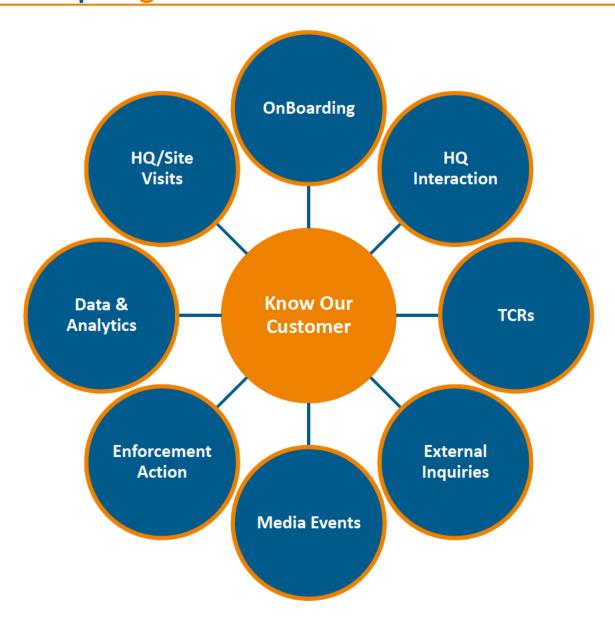
- ✓ Retail Diversion
- ✓ Special Investigations
- ✓ Data, Analytics & Intelligence
- ✓ Industry Leadership

## **Team Backgrounds / Skill Sets:**

- √ Regulatory Affairs
- ✓ Retail Diversion Analytics & Investigations
- ✓ Internal Data & Systems
- ✓ Distribution Center Operations
- ✓ Retail National Account Experience
- ✓ Project Management
- ✓ Clinical Research Compliance

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# McKesson CSMP | Diligence – "Know Our Customer"



## McKesson CSMP | Onboarding & Monitoring

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# **Onboarding**

## **Chain Diligence:**

- Pharmacy Operations
- ✓ CS Compliance Program & Policies
- ✓ Business Model / Processes
- ✓ Dispensing Data Review

## **Registrant Diligence:**

- ✓ Licensure & Registration
- ✓ Questionnaires (If Applicable)
- ✓ Dispensing Data (If Applicable)

## **Threshold Establishment**

# **Monitoring**

## **Ongoing Diligence:**

- ✓ Event Triggered Reviews
- ✓ Data Analysis Outlier Identification
- ✓ HQ Follow Up / Site Visits

## **Threshold Management (TCRs):**

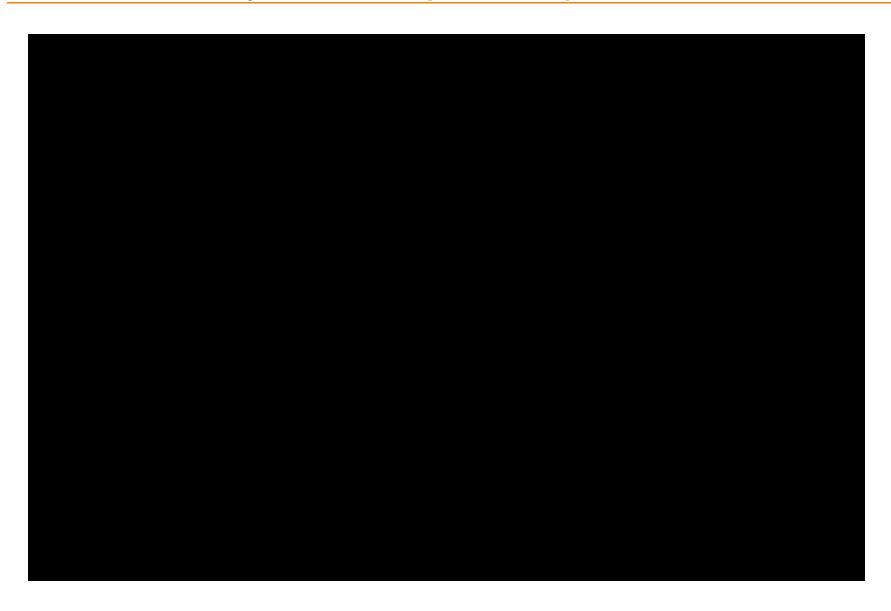
**Business Justification** 

- Dispensing Data
- ✓ Independent Retail Specific
  - Recent Questionnaire (12M)
  - Personnel Information

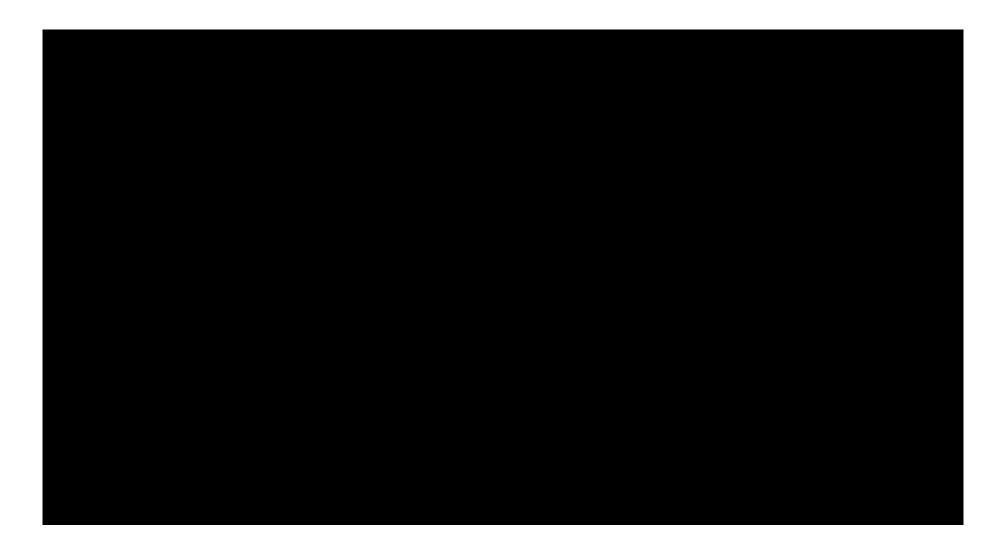
## **Suspicious Order Reporting**

# **Statistics, Analytics & Diversion Trends**

# McKesson CSMP | Data & Analytics Example



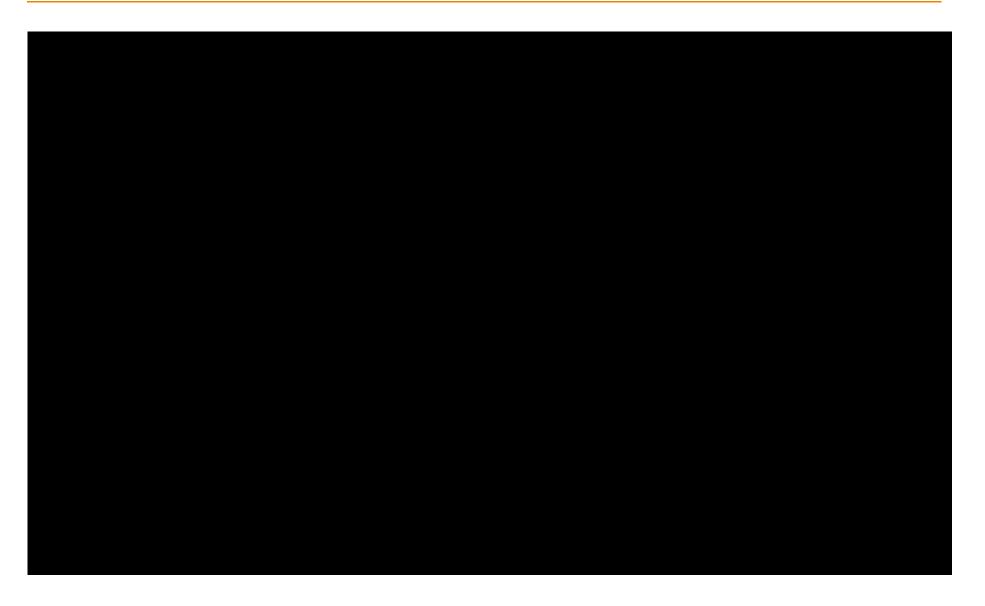
## McKesson CSMP | Data & Analytics Example



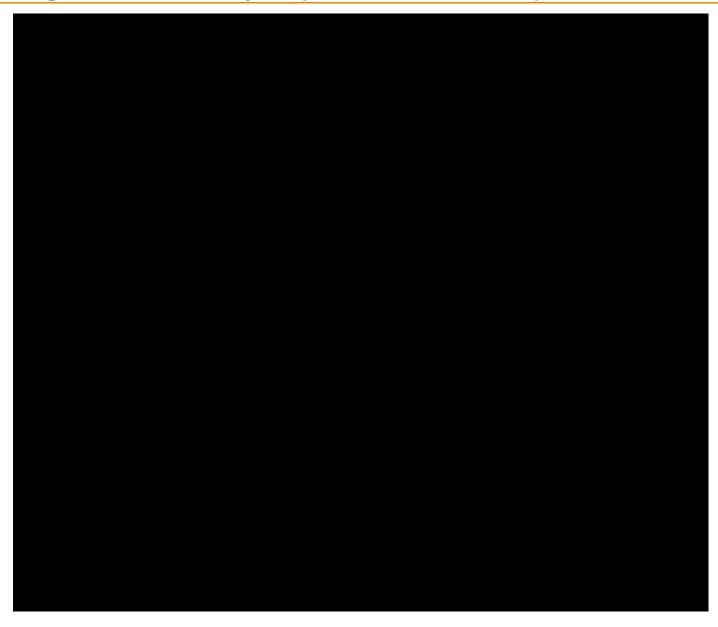
## McKesson CSMP | Data & Analytics Example



# **Dispensing Data Review | Chain Summary**



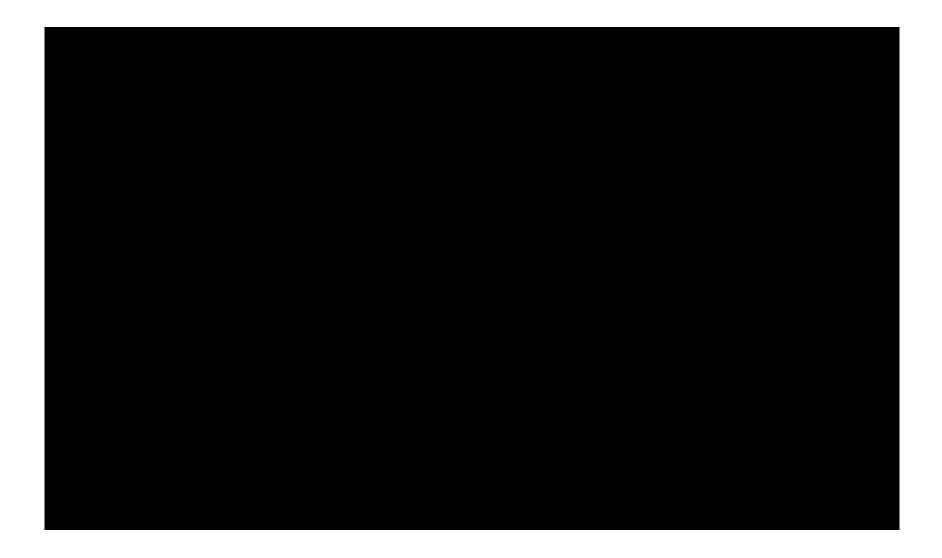
# **Dispensing Data Review | Oxycodone Heat Map**



# **Dispensing Data Review | Top Dispensing Lists**



# **Dispensing Data Review | Individual Pharmacy**



# **Dispensing Data Review | Individual Pharmacy**



## **Dispensing Data Review | Individual Pharmacy**



## McKesson CSMP | Education & Awareness

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## **Red Flags**

There are numerous "red flags" indicating possible prescription drug misuse, abuse and diversion. Some common red flags suggested by the DEA and certain state boards of pharmacy include:

## **Prescription Drug Al** Landscape

**Current Drug Abuse Trends** 



#### What Can You Do? Practical Tips

DEA registrants are always responsible for meeting the For pharmacists and pharmacy owners, this means ensu corresponding responsibility to determine that prescript medical purposes by practitioners acting in the usual cour One way in which the pharmacist and pharmacy owner car practices is to better understand their controlled substan data to circumstantially determine if diversion may be or

- for abuse, with those in schedule II having a higher pote Some of the more commonly diverted controlled substa hydrocodone, hydromorphone, oxymorphone, alprazol
- 2. Know your pharmacy's ordering patterns. What is y controlled substances to non-controlled substances? V of each controlled substance? What is your typical doss prescription? Maintaining awareness will help you rec

#### Pattern Prescribing

Pharmacists need to be particularly alert for prescriptions for the same drugs. quantities or diagnosis codes coming from the same doctor. Further, the use of rubber stamps is another key red flag.

#### Antagonistic Drugs

Look for prescriptions written for antagonistic drugs (e.g., depressants and stimulants).

#### **Drug Cocktails**

Flag and scrutinize prescriptions for drug cocktails (e.g., opioids with benzodiazepines and/or carisoprodol).

#### Large Quantities

Look at the quantities. High doses and/ or high quantities of drugs are often a key indicator of abuse.

#### **Doctor Patterns**

Be on the lookout for doctors that write significantly more prescriptions compared to other doctors in your area.

#### **Beyond Specialty**

Question prescriptions written by doctors 1. Closely monitor the drugs of concern. All controlleds for infirmaries not consistent with their area of specialty (e.g., dentist writing ADHD prescriptions).

#### Geographic Flags

Notice geographic anomalies, such as prescriptions written by a local prescriber for out-of-state patients, or situations in which the pharmacy is not near the patient or the prescriber.

#### **Unlikely Coincidences**

Situations such as customers with shared addresses presenting similar prescriptions from the same physician on the same day can also prove fraudulent.

#### **False Caregivers**

Further, you will want to scrutinize customers presenting prescriptions for other people.

#### **Cash Payments**

Customers paying cash may require additional scrutiny.

#### Early Refills

Customers requesting early refills of controlled substances should be questioned and may require additional scrutiny.

#### Suspicious Behavior

Look for signs of nervousness such as being overly talkative, agitated, emotionally volatile, evasive, etc.

#### Signs of Forgery

Fraudulent or forged prescriptions can often be identified by the following characteristics:

- · False contact information
- Misspellings
- Photocopies
- Alterations to prescriptions
- Different inks or handwriting
- · Quantity, directions or dosages differ from usual medical usage
- No abbreviations used or non-standard abbreviations

s national Automation nchmark in assessing rages of dosage units e DEA's 2012 ARCOS data.\* thing doesn't look right. se practitioner and use your and of pharmacy's wobsite at a reputation as being a oce and ensure that you

es controlled substances has pharmacies to be the last to working together with its

Doesge Units Annually
131,381
75,584
12,500
11,788
5,903
2,190

appropriate dispensing. They are simply national averages derived from the DEA's ARCOS data. Diversion can occur in as below the DEA national average

flags\* indicating possible prescription drug misuse, ne common red flags suggested by the DEA and certain

Unlikely Coincidences

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**Discount Drug Mart Program Overview** 

Q & A | Open Discussion

## **Controlled Substances | Discount Drug Mart CSMP**

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## **Discussion Topics:**

- Overview of Pharmacy Business
- Regulatory/Compliance Structure
- Policies & Procedures
- Training & Education
- Analytics, Monitoring & Follow Up
- Known Outliers

